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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,992	09/14/2000	Friedrich Scheiflinger	237.00	8902

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	19

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/661,992	SCHEIFLINGER ET AL.
Examiner	**Art Unit**
Maher M. Haddad	1644

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. There appear to be discrepancy regarding the disclosed sequences between the claims and the specification. For example, the claim 8 recites **amino acids** 1 to 357 and or amino acids 403 to 726 according to Fig. 14. While in the specification discloses **nucleotides** 1-357 code for the heavy chain variable domain, **nucleotides** 403 to 726 code for the light chain variable. Similarly, claims 10, and 12 recite amino acids for particular positions while the specification discloses nucleic acids for the same particular positions. Further, there appear to be discrepancy between the claims and the specification regarding the hybridoma names. For example claim 15, recites the cell line 193 K2-1 while the specification discloses the cell line 193 K2. Correction is required.

2. Applicant is reminded that "use" claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)).

For examination purposes "use" claim 24 is interpreted as a method of the first recited "use".

Restriction Requirement

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-4, 8-16, 18-19 and 23, drawn to an antibody against factor IX/factor IXa, hybridoma, pharmaceutical compositions thereof and a method of producing the antibody; classified in Class 530, subclass 387.3, and 391.1; Class 424, subclass 133.1 and 326.

II. Claims 1-2, 4-16, 18-19 and 23, drawn to an antibody derivative against factor IX/factor IXa, hybridoma, pharmaceutical compositions thereof and a method of producing the antibody; classified in Class 530, subclass 387.3, and 391.1; Class 424, subclass 133.1 and 326.

III. Claim 17, drawn to a DNA molecule encodes an antibody against factor IX/factor IXa, classified in Class 536, subclass 23.5.

IV. Claim 17, drawn to a DNA molecule encodes an antibody derivative against factor IX factor IXa, classified in Class 536, subclass 23.5.

V. Claims 20-22, drawn to a method for treating patients afflicted with blood coagulation disorders comprising administering a preparation of an antibody against factor IX/factor IXa; classified in Class 424, subclasses 133.1, and 141.1.

VI. Claims 20-22, drawn to a method for treating patients afflicted with blood coagulation disorders comprising administering a preparation of an antibody derivative against factor IX factor IXa; classified in Class 424, subclasses 133.1, and 141.1.

VII. Claim 24, drawn to a method for increasing the amidolytic activity of Factor IXa using an antibody against factor IX factor IXa ; classified in Class 435, subclass 7.2.

VIII. Claim 24, drawn to a method for increasing the amidolytic activity of Factor IXa using an antibody derivative against factor IX factor IXa ; classified in Class 435, subclass 7.2.

4. Groups I and IV are different products. Antibodies and DNA encoding the antibodies differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups V and VIII are different methods. A method for treating and a method for increasing differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups I-II and V-VIII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used for affinity purification, in addition to the methods of treating and increasing recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group V or VI is elected, applicant is required to elect a method for treating patients afflicted with blood coagulation disorders wherein the blood coagulation disorder is (a) hemophilia A diathesis or (b) hemorrhagic diathesis. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 20 is generic.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. A telephone call was made to Scott Ausenhus on 8/7/03 to request an oral election to the above restriction requirement, but did not result in an election being made. A written restriction was requested.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
August 25, 2003

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SUPERVISORY PATENT EXAMINER
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